STATE MEDICAID DUR BOARD MEETING

**THURSDAY, January 13, 2011**
**7:00 a.m. to 8:30 a.m.**
**Cannon Health Building**
**Room 114**

# MINUTES

**Board Members Present:**

**Neil Catalano, R.Ph.**
**Tony Dalpiaz, PharmD.**
**Wilhelm Lehmann, M.D.**
**Bradley Pace, PA-C**
**Kathy Goodfellow, R.Ph.**
**George Hamblin, R.Ph.**
**Cris Cowley, M.D.**
**Joseph Miner, M.D.**

**Board Members Excused**

**Mark Balk, PharmD.**
**Peter Knudson, D.D.S.**
**Bradford Hare, M.D.**
**Joseph Yau, M.D.**

**Dept. of Health/Div. of Health Care Financing Staff Present:**

**Richard Sorenson, R.N.**
**Tim Morley, R.Ph.**
**Heather Santacruz, R.N.**
**Merelyn Berrett, R.N.**
**Lisa Hulbert, R.Ph.**
**Angela Hanrdahan, R.N.**
**Marisha Kissell, R.N.**
**Jennifer Zeleny, R.N.**

**Other Individuals Present:**

Gary Oderda, U of U
Brooks Hubbard, Boehringer Ingelheim
Anne Marie Licos, Medimmune
Bryan Young, Purdue
Barbara Boner, Novartis
Jeff Buel, J&J
CarrieAnn Madden, U of U
Pat Wiseman, Medimmune
Roy Lindfield
Efrain Alton, Merck
Mark Germann, Novartis
Paul Latore, J&J

**Meeting conducted by:** Wilhelm Lehmann, M.D.

1 Review and Approval of Minutes: The minutes were reviewed. Kathy Goodfellow moved to approve the minutes. Neal Catalano seconded the motion. The minutes were approved unanimously by Neil Catalano, Kathy Goodfellow, Tony Dalpiaz, George Hamblin, Wilhelm Lehmann, Cris Cowley, and Brad Pace.

2 P&T Committee Report: BPH drugs will be reviewed in the February 17, 2011 P&T Committee meeting. In January, the P&T Committee reviewed Hormonal Contraceptives, and in December 2010, the P&T Committee reviewed Topical Acne Preparations.

3 Botox PA Criteria Update: Botox is now FDA approved for the prophylaxis of chronic migraines in adults. Medicaid would like to add this to the PA Criteria.

Neal Catalano moved to accept the updated PA Criteria. George Hamblin seconded the motion. The motion was approved unanimously by Neil Catalano, Kathy Goodfellow, Tony Dalpiaz, George Hamblin, Wilhelm Lehmann, Cris Cowley, and Brad Pace.

4 Pradaxa: Dr. CarrieAnn Madden from the University of Utah College of Pharmacy presented available evidence on Pradaxa and made recommendations on PA Criteria.

The Board asked how Dr. Madden would define "failure" of warfarin, since some of the recommendations include off-label use. Dr. Madden stated that she thought it would just include a statement from the physician.

Dr. Lehmann felt that this drug could be very appealing for physicians, since warfarin monitoring and coordination of care is very cumbersome. Additionally, Dr. Cowley stated that it was difficult to know the true cost of warfarin, since he sees many patients who have hospitalizations due to bleeds caused by warfarin. However, it troubled him that there was no antidote for Pradaxa.

Brooks Hubbard from Boehringer Ingelheim addressed the Board in favor the benefits of Pradaxa.

Robyn asked if Pradaxa needed to be discontinued before surgery, Mr. Hubbard stated the recommendations for how to handle surgery in patients on Pradaxa.

Lisa asked if there is any more information about myocardial infarction. Mr. Hubbard stated that there is no further information than what was in the studies. The risk was numerically higher with Pradaxa, but it was not statistically significant.

Neal Catalano asked if the statement about warfarin failure included both diagnoses listed in the PA criteria. Dr. Madden stated that she did not intend that, but the Board may want to consider it.

Dr. Lehmann stated that the Board may wish to not require warfarin failure. Iit may be sufficient for someone to be a poor candidate for warfarin.

The Board asked if Pradaxa was studied in pregnancy. Mr. Hubbard stated that it was not.

The Board asked if there were studies available for off-label use. This could be a very attractive drug for orthopedic surgery. Dr. Madden stated that there may be some applications for which there are studies available to support off-label use.

Tim stated that what the Board was considering about monitoring was mostly a convenience issue. If the Board does put a PA on Pradaxa to control it for a little while until more evidence becomes available, there would not be a problem accessing available therapy for those who needed.

Dr. Miner moved to accept the PA criteria as proposed, with the requirement for warfarin failure

attached to both diagnoses. The DUR Board felt that it was reasonable to allow access to off-label use until more data becomes available. Dr. Cowley seconded the motion. The motion was approved unanimously by Joseph Miner, Neil Catalano, Kathy Goodfellow, Tony Dalpiaz, George Hamblin, Wilhelm Lehmann, Cris Cowley, and Brad Pace.

5 Butrans: Robyn Seely presented available evidence about Butrans and proposed new Prior Authorization criteria.

Neal suggested that the PA criterion "reasonable belief that the patient is using the drug appropriately" should read "documentation that…". This would be based on early refill patterns in the Medicaid system or evidence obtained by the physician. The Board members felt that proposed change was a good idea.

The Board asked if the reauthorization period could be one year. The Board felt that was a reasonable change to request, because this PA was too much of a hoop to jump through every three months.

The Board asked if there are any criteria for fentanyl patches. Medicaid pays only 15 patches per month, and the 100mcg patches are for malignancy-related pain only. The fentanyl patches are one of several first-line agents on the PDL.

Dr. Miner asked if there was good evidence that the Butrans patch stays on for one week. The company actually studied patch peeling and buckling, and it turned out to not be a problem.

The Board asked how Medicaid would address titration. It was felt that more than 4 patches should be covered during the first and last month of therapy to account for escalation and de-escalation of dosing. This could currently be handled through overrides by Medicaid staff, but in the future the new point of sale system should be able to do this automatically.

Neal Catalano moved to accept the PA criteria with the modifications as discussed. Brad Pace seconded the motion. The motion was approved unanimously by Joseph Miner, Neil Catalano, Kathy Goodfellow, Tony Dalpiaz, George Hamblin, Wilhelm Lehmann, Cris Cowley, and Brad Pace.

The next DUR Board meeting was scheduled for Thursday March 10, 2011.

The DUR Board Prior Approval Subcommittee did not meet this month.

Minutes prepared by Jennifer Zeleny